

Permit Conditions for Self-Shielded Irradiators

Background

Authority to possess and operate irradiators is granted to an individual by the Radiation Safety Committee after the user's application has been reviewed and approved by the USDA Radiation Safety Staff (RSS).

It is the responsibility of the Permit Holder named on the Radiation Source Permit to comply with all safety and regulatory requirements of the Nuclear Regulatory Commission and the USDA Radiation Safety Program.

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**USDA License
and Program
Authority**

The authority to possess irradiators has been granted to the U.S. Department of Agriculture (USDA) by the Nuclear Regulatory Commission (NRC) in License 19-00915-06, as amended. This license applies to self-shielded dry-source storage irradiators within the United States.

Pool irradiators and self-shielded irradiators outside the United States are not covered by the NRC license but are managed through Departmental Regulation 4400-5: Radiation Safety Program. This regulation states Departmental policy relating to all sources of ionizing radiation.

Acquisition

Purchase orders for irradiators must be approved by the Radiation Safety Staff prior to the order being placed by a purchasing agent.

A Permit Holder must receive the prior approval from the RSS before an irradiator is transferred from another licensed or permitted individual.

Upon receipt of any irradiator, the following information must be submitted to the RSS:

- Sealed Source Inventory Record (RSS-28);
 - A copy of the manufacturer's leak test results; and
 - A copy of the manufacturer's information and specifications, such as a sales brochure.
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**Posting
Requirements**

The following information must be posted at the entrance to the irradiator room:

- NRC Form-3 "Notice to Employees";
- A "Caution - Radioactive Material" sign; and
- Emergency Contact information stating the following:

In the event of an emergency, immediately call the following:

USDA Radiation Safety Office:	(301) 734-4945
Local Radiation Protection Officer:	_____
Permit Holder:	_____
Facility Director:	_____

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General Safety Requirements

The following requirements shall be met at each facility:

- The irradiator shall be installed in a controlled or secured room or area;
- The room where the irradiator is located must be either:
 - equipped with an automatically operated fire detection and control system (such as sprinkler, dry chemical or gas) that is adequate to protect the integrity of the irradiator and source in case of a fire, or
 - located in a fire resistant building or area (one having little combustible materials) and other controls (fire alarms and training of fire-fighters) that ensure a very low level of radiation risk attributable to fires;
- The Permit Holder shall control keys to the room or area and to the irradiator;
- Safety interlocks, lights and other warning or control devices shall work properly at all times and be tested before the irradiator is used;
- With Gammacell 40 irradiators, an area radiation monitor shall be installed opposite the source drawer and set to alarm when a pre-set radiation level is exceeded. The pre-set level shall be determined after the initial radiation survey is completed; and
- The entrance to the controlled room or area shall be locked when an operator is not present.

Emergency Requirements

An emergency is considered to occur when a malfunction of the irradiator occurs causing the operator and other persons in the irradiator room or area to be potentially exposed to excessive radiation or to radioactive contamination. For example, an emergency would occur if the door to the sample chamber somehow disengaged, entered the source chamber and extensively damaged the source. In the event of an emergency:

- The operator shall immediately suspend all operations and evacuate all personnel except those investigating the emergency;
- The operator shall promptly notify the Permit Holder, the facility LRPO, the Facility Director, and the RSS;
- No further action shall be taken until the cause of the emergency is determined, evaluated and remedial action is prescribed by the RSS;
- A complete report shall be prepared detailing the circumstances of the emergency, identification of the persons involved, observed radiation levels, and duration of exposure as well as results of the area survey and any related details.

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**Requirements in
the Case of Fire**

The following requirements shall be met at each facility:

- In case of fire in the immediate area or in an adjacent building, operation of the irradiator shall be suspended and the irradiator shall be closed and locked;
 - The fire company shall be promptly notified;
 - Firefighters shall be advised of the potential hazard by the Permit Holder or other individual;
 - After the fire, the entire area shall be surveyed for contamination and the irradiator surveyed for any loss or change of shielding integrity before the area is opened to reconstruction or returned to service;
 - The USDA Radiation Safety Officer shall determine a course of action and shall notify the NRC in accordance with Federal regulations; and
 - A complete report shall be prepared detailing the circumstances of the fire, identification of persons involved, observed radiation levels and duration of exposure as well as results of the area survey and related details.
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Leak Tests

A leak test of the irradiator must be performed at intervals not to exceed six months.

The test must be performed in accordance with the manufacturer's instructions. The use of remote handling tools to wipe an accessible surface where contamination may be deposited is recommended.

The RSS will supply leak test kits, perform the required analysis, and report the results back to the Permit Holder. The Permit Holder can use other companies to perform and analyze the leak test provided they are properly licensed to perform that service. It is the responsibility of the Permit Holder to supply a copy of the company's license to RSS for verification.

**Leak Test
Limits**

A sealed source has failed the leak test when the contamination on the filter paper used for the test exceeds 0.005 μCi (11,100 DPM). Devices exceeding this level are to be removed from service, and returned to the manufacturer for repair, replacement, or disposal.

The USDA ALARA program uses one other limit to monitor the performance of these tests.

- 1,110 DPM (10% of the limit) is a notification level. Users of devices exceeding this level will be notified of the test results to make them aware of the potential for source leakage in the future.
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Authorized Users	Only the Permit Holder and the Associate Users listed in the Permit are authorized to operate an irradiator.
Training Requirements	The Permit Holder and the Associate Users must receive basic radiation protection training and pass an examination administered by the USDA Radiation Safety Staff or other approved trainer.
Personnel Monitoring	<p>All individuals who use an irradiator shall wear a radiation dosimeter (film badge) assigned to them.</p> <p>The dosimeter shall be stored away from areas of extreme heat, cold or humidity when not in use.</p> <p>NOTE: For more detailed information on dosimetry, refer to the USDA Permit Condition on Personnel Monitoring.</p>
Radiation Survey Instrumentation	Each facility possessing and operating an irradiator shall have on hand at least one properly operating radiation survey meter. Instruments shall have a detection range from 0.1 to 100 mR/hr. Instruments shall be recalibrated at an interval not to exceed one year, or when the instrument fails to respond properly to a check source or after servicing.
Radiation Survey Requirements	Upon installation and before initiation of an irradiation program, a thorough survey of the irradiator shall be made to determine radiation levels on the top, bottom, all sides of the unit, and at the operator's position. Readings shall be taken at two (2) inches from the surface and at three (3) feet with the source in the irradiate position and in the shielded position. The readings shall be recorded on an appropriate survey form and placed on file. A copy shall be sent to the RSS. Additional radiation level surveys shall be performed on an annual basis.
Maintenance	<p>All servicing or cleaning of an irradiator involving exposure of the radioactive source (non-routine maintenance) must be performed by the manufacturer or by an authorized representative of the manufacturer.</p> <p>Routine maintenance may be performed by the Permit Holder.</p> <p>After any maintenance of the irradiator, the Permit Holder will assure that the irradiator is operating properly, perform a radiation survey, and verify the proper operation of all emergency controls and interlocks.</p>

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**Disposal of
Unused
Irradiators**

The proper disposal or transfer of unused irradiators is required. Irradiators should not remain unused in any facility for extended periods of time.

Prior to disposing or transferring any irradiator, the Radiation Safety Staff must be notified. This allows the RSS to:

- Perform a records check;
- Verify that a current leak test is available for the device prior to shipping;
- Determine if there are any special shipping or packaging requirements;
and
- Amend the user's radioactive materials permit.

The disposal can be accomplished only after the written approval of the RSS is received by the Permit Holder.

Copies of all shipping documents must be sent to the RSS for placement in the archive file maintained for all sealed radioactive sources.

Records Retention

All documents relating to the purchase, transfer, or disposal of an irradiator must be retained by the Permit Holder for as long as the permit is active.

The Radiation Safety Staff maintains records of the purchase, transfer, and disposal of an irradiator as long as the Department's radioactive materials license is active.

Records of leak tests and annual radiation surveys must be retained for three years. Both the permit holder and the Radiation Safety Staff must retain these records.

Questions

If there are any questions regarding the information in this document, contact:

USDA Radiation Safety Staff
5601 Sunnyside Avenue
Mail Stop 5510
Beltsville, MD 20705

Phone: (301) 504-2440

Fax: (301) 504-2450

Approved:

3/11/96

Date

By:

/s/

John T. Jensen

Director, Radiation Safety Staff